

REMARKS

The Office Action dated October 3, 2005 has been carefully considered. The present Amendment, taken with the accompanying remarks, is believed sufficient to establish the patentability of the claims and place the present application in condition for allowance. An early allowance is respectfully requested.

Claim 1 has been amended to incorporate the limitations of claims 15 and 17, which have been cancelled accordingly. Claims 31 and 32 are amended to correct the resulting inaccuracy in dependency. Claim 53 has been amended to reflect the changes in the composition defined by amended claim 1. As these changes do not involve new matter, it is believed that entry is in order and is thereby respectfully requested.

Claims 1-14, 16, and 18-58 are pending in the application and subject to examination.

35 U.S.C. § 102

Claims 1-16, 18-30, 33-43, 49, 51 and 53-55 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Application Serial No. 5,879,666 to Lucas et al (Lucas '666) or U.S. Application Serial No. 5,874,067 to Lucas et al. (Lucas '067) (collectively, '666 and '067 are referred to herein as "the Lucas patents"). Specifically, the Examiner asserts that the Lucas patents disclose odor-absorbing compositions comprising up to 5% of uncomplexed cyclodextrin (CD), emulsifiers such as those described instantly, and citric acid, which is safe for human skin. The Examiner further points to examples I-III of Lucas as assertedly disclosing the specific castor oil surfactant recited in instant claim 1. The Examiner maintains that the claim limitations regarding the % and the level of functionally available CD are inherent in the compositions of Lucas because the uncomplexed CD disclosed "is the same amount as claimed," and further

maintains that Lucas discloses the same surfactants as claimed and hence the critical micelle concentration and Clog P values claimed are inherent to the surfactants of Lucas. This rejection is traversed and reconsideration is respectfully requested.

Instant independent claim 1 is directed to a composition suitable for capturing unwanted molecules from a surface. The composition comprises functionally-available cyclodextrin; a cyclodextrin-compatible surfactant selected from the group consisting of castor oil surfactant, polyethoxylated fatty alcohol surfactant, polypropoxylated fatty alcohol surfactant, glycerol mono-fatty acid ester surfactant, polyethylene glycol fatty acid ester surfactant, polypropylene glycol fatty acid ester surfactant, fluorocarbon surfactant, and mixtures thereof; and a cyclodextrin-incompatible surfactant having a ClogP value of at least about 3, wherein the composition comprises molecular aggregates comprising said cyclodextrin-compatible surfactant and said cyclodextrin-incompatible surfactant, and further wherein the concentration of functionally-available cyclodextrin, as applied to the surface, is at least about 0.001%.

Instant independent claim 53 is directed to a composition suitable for capturing unwanted molecules from a surface. The composition, as applied to the surface, comprises: at least about 0.001% of functionally-available cyclodextrin; a cyclodextrin-compatible surfactant selected from the group consisting of castor oil surfactant, polyethoxylated fatty alcohol surfactant, polypropoxylated fatty alcohol surfactant, glycerol mono-fatty acid ester surfactant, polyethylene glycol fatty acid ester surfactant, polypropylene glycol fatty acid ester surfactant, fluorocarbon surfactant, and mixtures thereof; a buffering agent having at least one pK_a value and/or pK_b value of from about 2 to about 11; a cyclodextrin-incompatible surfactant having a ClogP value of at least about 3, wherein the composition comprises molecular aggregates comprising said cyclodextrin-compatible surfactant and said cyclodextrin-incompatible surfactant; and a

cyclodextrin-compatible antimicrobial active, wherein the composition has a pH of from about 3 to about 9.

Instant independent claims 1 and 53 explicitly require that the CD be functionally available, not just as added to the composition, but at the surface of the substrate having unwanted molecules. Hence, CD is "functionally available" within the meaning of the present claims, applies not just because it is uncomplexed or weakly complexed CD, but because its cavity is protected from access by strongly complexing molecules. Functionally available CD must exist in the composition at competitive equilibrium with the other components of the composition, such that the CD is functionally available *to bind with unwanted molecules on a surface*. If they bind, instead, with strongly complexing molecules present in the composition itself, prior to contact with a surface, then they are not functionally available within the meaning of the present claims.

The Lucas patents are directed to compositions and methods for controlling odor on human skin. While the Lucas patents disclose compositions comprising "uncomplexed cyclodextrins," they fail to disclose compositions comprising functionally available cyclodextrin in combination, inter alia, with cyclodextrin-compatible *and* cyclodextrin-incompatible surfactants, organized into molecular aggregates, as required in the compositions defined by instant claims 1 and 53. The organization of the cyclodextrin-incompatible surfactant into molecular aggregates reflects the result of a particular process of manufacturing the inventive compositions, as presently disclosed, and, significantly, permits the addition of cyclodextrin-incompatible surfactants into compositions of cyclodextrins, without the expected complexation that would result in functional unavailability of the cyclodextrin (see "Process of Manufacture," page 42, bridging to page 43). The mere disclosure of compositions comprising uncomplexed

cyclodextrin, cyclodextrin-compatible surfactants, and cyclodextrin incompatible surfactants (or any other cyclodextrin incompatible materials) would not anticipate the present claims because, inter alia, without formulation according the present teachings, the cyclodextrin-incompatible material, rather than being organized into molecular aggregates with the cyclodextrin-compatible surfactant, will be free to complex with the uncomplexed cyclodextrin, rendering the initially uncomplexed cyclodextrin functionally unavailable.

Anticipation under 35 U.S.C. § 102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). Moreover, to serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). The Lucas patents fail to teach, inter alia, compositions comprising functionally available CD suitable for capturing unwanted molecules from a surface, cyclodextrin-compatible and incompatible surfactant, wherein the surfactant is organized into molecular aggregates, as required by the present claims. Moreover, the teachings of the Lucas patents do not enable the present invention, as they do not teach the requisite process for molecular aggregate organization and do not disclose it inherently, and therefore do teach all the elements of the instant independent claims. Hence, the rejection of claims 1-16, 18-30, 33-43, 49, 51 and 53-55 under 35 U.S.C. § 102(b) has been overcome and reconsideration is respectfully requested.

35 U.S.C. § 103

Claims 44, 50, 52 and 56-58 are rejected under 35 U.S.C. § 103 as being unpatentable over Lucas '666 or Lucas '067 (collectively, "the Lucas patents"), in view of U.S. Patent No. 5,942,217 to Woo et al. (Woo). Specifically the Examiner notes that neither Lucas patent teaches the use of the compositions in a fabric softener, on a fabric, or for hard surfaces, and that neither discloses the specific quaternium antimicrobial compounds and the pH recited in instant claim 58. The Examiner asserts that Woo teaches compositions comprising uncomplexed cyclodextrin for absorbing odor from inanimate surfaces, particularly from clothes and fabric, and that Woo describes the same uncomplexed cyclodextrins as that of the Lucas references, as well as that of the instant invention. The Examiner further asserts that Woo teaches inclusion of cyclodextrin-compatible surfactants along with uncomplexed cyclodextrins for absorbing odors from fabrics, and the inclusion of antimicrobial compounds such as betaines, quaternary ammonium compounds, etc, in the cyclodextrin composition for their antimicrobial action. The rejection is traversed and reconsideration is respectfully requested.

Independent claims 1 and 53 are set forth in detail above.

The deficiencies of the Lucas patents with respect to independent claims 1 and 53 are discussed above. Woo fails to address these deficiencies. In particular, Woo fails to teach or suggest compositions comprising, inter alia, cyclodextrin-compatible and incompatible surfactant organized into molecular aggregates, and functionally available cyclodextrin. Woo teaches aqueous, odor-absorbing compositions comprising cyclodextrin in combination with cyclodextrin-compatible ingredients, including cyclodextrin-compatible surfactant and cyclodextrin-compatible antimicrobial actives (column 1, lines 8-20).

Applicants submit that not only do the Lucas patents in combination with Woo, fail to teach or disclose the compositions recited in claims 1 or 53, neither do they *suggest* the inventive

compositions. Further, the teachings of the Lucas patents in view of Woo, taken as a whole, fail to enable the present inventive compositions. The asserted combination fails to teach or suggest compositions comprising, inter alia, functionally-available cyclodextrin, suitable for capturing unwanted molecules from a surface, cyclodextrin-compatible and incompatible surfactant organized into molecular aggregates, wherein the concentration of functionally-available cyclodextrin, as applied to the surface, is at least about 0.001. The combination fails to teach the processes which promote the organization of the cyclodextrin-compatible and incompatible surfactant into molecular aggregates, which essentially prevents complexation of the cyclodextrin-incompatible surfactant with the uncomplexed cyclodextrin, yielding a composition comprising functionally-available cyclodextrin, despite the presence of cyclodextrin-incompatible surfactant or other cyclodextrin-incompatible materials.

The present inventive compositions represent a significant improvement over the art, as it permits the inclusion of surfactants heretofore discouraged for use with cyclodextrin in applications such as odor control on a surface, where functionally available cyclodextrin is desired. For example, in aqueous solutions provided for laundry applications, complexing of the cyclodextrin with surfactant decreases the ability of the surfactant to lower the surface tension of the solution, known in the art as an important consideration in efficacy. Compositions according to the present invention comprise surfactant, organized into molecular aggregates, which do not typically access the cyclodextrin cavity. Hence, not only is a wider variety of surfactant permitted in the present inventive compositions, with retention of cyclodextrin efficacy, the surface-tension reducing capacity of the surfactant itself is enhanced (see, e.g. specification, page 8) relative to other cyclodextrin compositions.

To establish prima facie obviousness of the claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Furthermore, references relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). The combination of the Lucas patents in view of Woo, fail to teach or suggest compositions comprising functionally available CD, in combination with, inter alia, cyclodextrin-compatible and cyclodextrin-incompatible surfactant organized into molecular aggregates, suitable for capturing unwanted molecules from a surface. Further, none of the asserted patent references teach formulation processes which would inherently result in the presently inventive compositions, or disclose examples or illustrations which incorporate or reflect this teaching. There is no teaching in any of the asserted references of how to formulate compositions that comprise both cyclodextrin-compatible and cyclodextrin-incompatible surfactant, according to the present invention, and that result in compositions comprising the requisite functionally available cyclodextrin.

Therefore independent claim 1 and claims 44, 50, 52 and 58 dependent therefrom, and independent claim 53, and claims 56-57 dependent therefrom are nonobvious and patentably distinguishable from the Lucas patents in view of Woo. Hence, the rejection of claims 44, 50, 52, and 56-58 under 35 U.S.C. §103 under the Lucas patents, in view of Woo, has been overcome. Reconsideration is respectfully requested.

Claims 17, 31, 32 and 45-48 are rejected under 35 U.S.C. §103 as being unpatentable over Lucas '666 or Lucas '067 (collectively, "the Lucas patents). Specifically, the Examiner notes that neither of the Lucas patents teaches the claimed method of preparation and aggregate formation between cyclodextrin compatible and cyclodextrin incompatible surfactants, and then

adding cyclodextrin to form a mixture. The Examiner, however, asserts that the Lucas references "teach sulfosuccinate surfactants and other anionic surfactants which is described in the instant specification as cyclodextrin incompatible surfactants." The Examiner asserts that the Lucas patents "teach preparation of the compositions in different ways, mixing all the ingredients together or pre-combining less than all the ingredients," and accordingly, concludes that "absent evident to the criticality of the steps in the claimed processes, it would have "been within the scope of a skilled artisan at the time of the instant invention to prepare the instant composition by combining all the ingredients in one step or mixing the components in different phases without affecting the final performance of the composition." This rejection is traversed and reconsideration is respectfully requested.

Present independent claim 1, which incorporates the recitation of former dependent claim 17, is set forth in detail above.

Present independent claim 45 is directed to a process of manufacturing a composition suitable for capturing unwanted molecules from a surface. The process comprises the steps of: providing cyclodextrin, a cyclodextrin-compatible surfactant, and a cyclodextrin-incompatible material; combining said cyclodextrin-compatible surfactant and said cyclodextrin-incompatible material to form a first mixture, wherein said cyclodextrin-incompatible material is maintained in molecular aggregates in said first mixture; and subsequently combining said cyclodextrin with said first mixture to form said composition suitable for capturing unwanted molecules from a surface, wherein said composition comprises functionally available cyclodextrin.

Applicants submit that, as taught in the present specification at page 23, bridging to page 24, the process embodiment of claim 45 provides a formulation process whereby components that previously were avoided in compositions comprising uncomplexed CD, because they would

competitively bind with the CD, may be included in CD compositions such that the CD remains functionally available and the composition is suitable for capturing unwanted molecules. Specifically, as disclosed in the specification at page 23, lines 11-13 and recited in claim 45, compositions can be carefully formulated, to comprise both CD-incompatible materials and functionally available CD.

The Lucas patents, on the other hand, do not disclose significance to the order of component addition or any other adaptation of their formulations which would prevent access by the CD-incompatible materials, to the cavity of the CD. The Examiner appears to be asserting that the Lucas disclosures establish a prima facie case because they disclose random formulation orders, but the Examiner overlooks the insufficiency that the Lucas patents fail to disclose compositions comprising cyclodextrin-compatible and cyclodextrin-incompatible surfactants organized into molecular aggregates. That is, the Lucas patents fail to disclose or suggest an element of the composition as recited in claim 1, as well as the process step recited in claim 45.

The Lucas patents teach "variations of processes of making the compositions (col. 10, lines 58-60), including pre-combination of some ingredients, but, significantly, fail to disclose the ingredients required by the present claims in any order. Lucas fails to disclose the ingredient *of cyclodextrin-compatible and cyclodextrin-incompatible surfactants organized into molecular aggregates*. Further, Lucas '067 illustrates what is meant by this "pre-combination" in Examples I-III (column 12), all of which disclose preparation of a "premix." In Example I, the "premix" is water and a surfactant, which is then combined in a subsequent step with an aqueous solution comprising the CD. In Example II, the premix is a known antibacterial agent and an oil. In Example III, the premix is water and surfactant, which is subsequently mixed with an aqueous solution, and then mixed again with a second aqueous solution comprising the CD. Applicants

submit that the Lucas patents fail to disclose the pre-mixing of a cyclodextrin-compatible surfactant and a cyclodextrin-incompatible surfactant, as required by claim 45, fail to disclose the formation of molecular aggregates of these surfactants at any point during the process, or compositions comprising such aggregates, as required by claims 45 and 1 respectively, and fail to disclose or suggest any functional motivation or basis for doing so. As the present specification teaches, the order of addition of the components, and the organization of the cyclodextrin-incompatible material into molecular aggregates, enables the formulation of the present compositions.

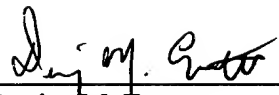
The Lucas patents do not teach or suggest importance of order, and, contrary to the Examiner's assertion, the Lucas patents do not disclose the order *required as an element* by present independent claim 45, and disclosed by the present specification as key to the enablement of the compositions defined by present independent claim 1. Applicants fail to find any compositions disclosed in the Lucas patent references, comprising cyclodextrin-compatible and incompatible surfactant organized into molecular aggregates, and fail to find any examples or disclosures of processes which would inherently yield this element. Applicants submit that their discovery, that mixing certain CD-compatible and CD-incompatible materials together prior to the addition of CD such that the CD-incompatible materials are maintained in molecular aggregates and not accessible to the cavity of the CD, permits the formulation of compositions comprising both CD-incompatible material and functionally available CD and is novel and patentably distinguishable over the known art, including the Lucas patents, both with respect to the composition and to the method.

To establish prima facie obviousness of the claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580

(CCPA 1974). Furthermore, references relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). The Lucas patents fail to teach or suggest methods comprising, inter alia, combining a cyclodextrin-compatible surfactant and the cyclodextrin-incompatible material to form a first mixture, wherein the cyclodextrin-incompatible material is maintained in molecular aggregates in the first mixture and subsequently combining the cyclodextrin with the first mixture to form the composition suitable for capturing unwanted molecules from a surface, wherein the composition comprises functionally available cyclodextrin, as required by instant claim 45. The Lucas patents fail to teach or suggest compositions comprising, inter alia, cyclodextrin-compatible surfactants and cyclodextrin-incompatible surfactants organized into molecular aggregates, and functionally available cyclodextrin, as required by instant claim 1. The Examiner's assertion that the Lucas patents establish a prima facie case of obviousness because they disclose various, random orders of addition of ingredients, overlooks the insufficiency of disclosure with respect to the ingredients themselves, and overlooks the insufficiency with respect to the specific, requisite order presently disclosed and claimed. Hence, independent claim 1 and independent claim 45 and claims 46-48 dependent therefrom, are patentably distinguishable from the Lucas patents and the rejection is overcome. Reconsideration is respectfully requested.

It is believed that the foregoing constitutes a complete and particularized response to the rejections of claims 1-58 under 35 U.S.C. §§ 102 and 103. Reconsideration and an early allowance is respectfully requested.

Respectfully submitted,

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